JAN 1 1 2001 K003485

510(k) Summary

CyberCare, EHC400 Desktop Patient Station
CyberCare, EHC600 Care Provider Station
CyberCare Weight Scale

The following information is submitted in accordance with 21 CFR 807.92

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Contact Person: Gordon J. Peters, Director Regulatory Compliance
Date Prepared October 12, 2000

Name of Device

CyberCare EHC400 Desktop Patient Station /EHC600 Care Provider Station

Device Classification/Classification Panel

EHC400/EHC 600 as:

21 CFR 890.3710 Powered Communication System	ILQ	Class II
21 CFR 870.1130 Noninvasive Blood Pressure Measuring Systems	DXN	Class II
21 CFR 880.2910 Clinical Electronic Thermometer	FLL	Class II
21 CFR 870.2700 Noninvasive Pulse Oximeters	DQA	Class II
21 CFR 870.1875 (b), (1) Electronic Stethoscope	DQD	Class II
21 CFR 862.1345 Glucometer	CGA	Class II
21 CFR 880.2720 Weight Scale	FRW	Class I

Predicate Device

CyberCare EHC400 Desktop Patient Station/EHC600 Care Provider Station, E-Scope ™.

Intended Use

The CyberCare EHC400 Desktop Patient Station (EHC400) is a patient monitoring system intended for providing out-of-hospital vital signs monitoring of adult patients or pediatric patients with the assistance and supervision of an adult. The EHC400 is intended to work in conjunction with the EHC600 Care Provider Station (EHC600) providing two-way video, audio and data communication between the two stations. The EHC400 provides the following physiologic functions: noninvasive blood pressure (NIBP), oximeter (SpO_2), heart rate, electronic oral thermometer, an electronic stethoscope, blood glucose monitoring and the additional intended use of a weight scale.

Description of the Device/Substantial Equivalence

The Company's EHC400, with the additional intended use of a weight scale, covered by this submission, is substantially equivalent to the predicate CyberCare EHC400 Desktop Patient Station (EHC400) that has already been cleared by FDA, pursuant to K000237. The EHC400 with electronic weight scale has the same general intended use, same principles of operation, and same technological characteristics as the EHC400. The EHC400 with the weight scale and its predicate device are both intended for providing out-of-hospital vital signs monitoring of adult patients, or pediatric patients with the assistance and supervision of an adult. They both consist of a touch screen computer and a vital signs unit providing monitoring of noninvasive blood pressure (NIBP), oximeter (SpO_2), heart rate, and electronic oral thermometer, electronic stethoscope, and blood glucose monitoring. The difference is the addition of an electronic weight scale feature. The operating software of the EHC400 with the weight scale is the same as for the EHC400 predicate device.

The EHC400, installed where the patient can conveniently access it, is designed to be used with the EHC600, which is also cleared as part of K000237, remotely located at the office of a professional care provider. The two stations modem connected by standard phone lines or a digital transmission service provide real-time audio and video communication between the patient and the caregiver. Blood pressure, blood oxygenation saturation and pulse rate, oral temperature electronic stethoscope to amplify heart, lung, and bowel sounds blood glucose monitoring and the additional intended use of a weight scale are transmitted over the communication link for display on the EHC600.

Performance Data

The EHC400 with the additional intended use of a weight scale uses currently available technology found in legally marketed devices. Testing, to ensure that the EHC400 with weight scale would perform as intended, was conducted at two levels: Non-clinical bench testing to test each function and clinical testing using volunteers to verify performance of the weight scale The EHC400 with weight scale and the EHC600 meets applicable standards for performance and EMC compliance.

Non-clinical Testing

Testing was performed to evaluate the functional modules within the predicate EHC400. These tests were repeated on the EHC400 containing the electronic weight scale the testing shows that the vital signs modules in the EHC400 with the electronic weight scale operate substantially the same as those in the predicate EHC400.

Clinical Testing

Clinical testing was performed on 25 volunteer subjects under an appropriate IRB approved protocol. All weight scale comparisons were taken with the individual standing adjacent to the Patient Desktop Station (EHC400) in a normal operating environment. The testing shows that the CyberCare Electronic weight scale functioned favorably.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 11 2001

Mr. Gordon J. Peters
Director Regulatory Compliance
CyberCare Technologies, Inc.
Building 300, Suite 320
7840 Roswell Road
Atlanta, GA 30350

Re: K003485
CyberCare EHC400 & EHC600 Desktop Patient Stations
Regulatory Class: II (two)
Product Code: DQD
Dated: October 12, 2000
Received: October 18, 2000

Dear Mr. Peters:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4645. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known) K003485

Device Name: CyberCare EHC400 Desktop Patient Station/
EHC600 Care Provider Station

Indications for Use:

The CyberCare EHC400 Desktop Patient Station (EHC400) is a patient monitoring system intended to provide out-of-hospital vital signs monitoring of adult patients or pediatric patients with the assistance and supervision of an adult. The EHC400 is intended to work in conjunction with the CyberCare EHC600 Care Provider Station to provide two-way video, audio and data communication between the two stations. The system monitors the following physiologic functions: blood pressure (sphygmomanometer), oxygen saturation (pulse oximeter), heart rate (pulse oximeter), temperature (electronic oral thermometer) amplifies heart, breath, and bowel sounds (electronic stethoscope) blood glucose (Glucometer) and weight scale monitoring.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003485

Prescription Use X OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)